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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/814,764	03/31/2004	Eric R. First	17672 (BOT)	8867

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EXAMINER	
PORTNER, VIRGINIA ALLEN	
ART UNIT	PAPER NUMBER
1645	
MAIL DATE	DELIVERY MODE
06/27/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/814,764	FIRST, ERIC R.	
	Examiner	Art Unit	
	Ginny Portner	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *12 April 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,5,6,13-15,19 and 20* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,5,6,13-15,19 and 20* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claims 1, 5-6, 13-15, 19 and 20 are pending.

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on April 12, 2007 has been entered.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Amended Claim 13 rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

4. Claim 13 has been amended to first administer botulinum toxin to a pressure sore, followed by debrding the pressure sore.

5. Upon consideration of the disclosure in the instant Specification, the only support for deriding combined with botulinum toxin was found in Example 4. The narrative from Example 4 is provided immediately below.

6. Example 4 Use of a Botulinum Toxin to Treat Pressure Sores Related to Immobility

[0113] An 43 year old woman is admitted following a fall from a ten story building. Two months post admission the patient begins to develop significant pain and tenderness in her sacral region. On admission to rehabilitation, the patient is evaluated and placed on a stage III mattress overlay. Prior to this the patient has been lying prone since her admission to acute care. It is recommended that the patient begin a course of botulinum toxin to prevent progression to stage IV pressure sores. **After debridement, 100 units of a botulinum toxin type A** admixed into vehicle comprised of bacitracin ointment and is applied **topically in a concentration of 1 unit/ml of ointment and applied as 1 unit botulinum toxin/cm2**. Four 4 weeks later, significant reduction in size of the pressure sore is noted, and pain and discomfort are.

The method of Example 4 comprised **debridment followed by topical** administration of botulinum toxin, and not botulinum toxin administered by any mode of administration followed by debriding the sore. The instantly claimed sub-genus of species does not evidence original descriptive support in the instant Specification and therefore constitutes New Matter.

Claim Rejections - 35 USC § 102

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an

international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

8. Claims 1, 5- 6 , 15, 19 and 21 are rejected under 35 U.S.C. 102(e) as being anticipated by Dake et al (US PG-Pub 2005/0196414, effective filing date March 3, 2004).

Please Note: The following prior art rejection is being made of record in light of Applicant's definition provided at page 3, which includes 4 stages, which include anal fissures and buttocks wounds.

9. Dake et al disclose the instantly claimed invention directed to a method, the method comprising the step of : administering botulinum toxin type A (see page 14, claim 6) topically to the buttocks of a patient for wound healing (see pages 15-17, claims 51, 54, 71, 126 and 141) or an anal fissure (see page 2, [0012, col. 2, lines 6 and [0013 topical application]) for the desired therapeutic effect ([0013]).

The topical administration dosage for botulinum toxin[0044 "type A", [0047 "dermatologically"] includes 1 U/cm^2 ([0058] .

Dake et al anticipates the instantly claimed invention as now claimed.

10. Claims 1 are rejected under 35 U.S.C. 102(b) as being anticipated by Brisinda et al (1999). **Please Note**: The following prior art rejection is being made of record in light of Applicant's definition provided at page 3, which includes 4 stages, which include anal fissures and buttocks wounds.

Brisinda et al disclose the instantly claimed invention directed to a method that comprises the steps of :

Administering serotype A (see page 66, col. 1, "Treatment" section, BOTOX) botulinum toxin (see title) to a pressure sore (see page 66, col. 1, p. 1 "A reduction in the anal pressure for three or more

months allows the fissure to heal and thus eliminates the need for surgery), the pressure sore of Brisinda et al being an anal fissure which is the result of increased resting pressure (see Table 2, page 67, col. 2) associated with chronic anal fissure and with botulinum toxin treatment, the resting pressure is reduced permitting healing of the pressure sore(see page 68, col. 2, "treatment with either nitrates or botulinum toxin was effective").

Brisinda et al anticipates the instantly claimed invention as now claimed.

Claim Rejections - 35 USC § 103

11. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

1. Claims 1, 5-6, 14-15,19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rebar et al(2003/0021776 A1) in view of Borodic (PG Pub 2002/0187164) and Gassner (US Pat. 6,447,787).

Rebar et al describe, suggest and teach of method of treating a pressure sore (see [310]) by subcutaneously [0291] administering a composition that comprises a Clostridial toxin (see[0275] Clostridium perfringens iota toxin) together with a zinc finger protein (ZFP), the toxin being used to translocate the ZFP across a cell membrane, but differs from the instantly claimed invention by failing to show the Clostridium toxin to be Clostridium botulinum toxin, specifically Clostridium botulinum toxin A.

Borodic teach Clostridium perfringens iota toxin, and Clostridium botulinum toxin C2 toxin to be functional equivalents (see Borodic [0028]) in an analogous art for the purpose of topically treating a patient for the reduction of inflammation with a composition that comprises a Clostridium toxin, specifically botulinum toxin C(see claims 8-9, 12). Gassner et al teaches and shows Clostridium botulinum toxin C2 and type A (see Gassner col. 3, lines 43-46) both to function as chemodeneverating agents in an analogous art for the purpose of enhancing skin, tendon and bone wound (see Gassner, title, abstract, col. 3, lines 6-8) healing through minimizing the adverse effects of muscle tension and movement on the wound (see Gassner, col. 3, lines 37-39) during wound healing (see Gassner claim 6).

It would have been obvious to the person of ordinary skill in the art at the time the invention was made, to modify the method of treating a pressure sore of Rebar et al that administers a Clostridial toxin containing composition with the Clostridial toxin, specifically Clostridium botulinum toxin type A of Gassner because

Rebar et al, Borodic and Gassner are directed to treating conditions associated with inflammation through the administration of a Clostridial toxin, to include pressure sores inflammatory wounds and

Borodic teaches the Clostridial toxin of Rebar et al to be a functional equivalent of Clostridium botulinum toxin C2 and Gassner et al teach Clostridium botulinum toxin C2 as taught by Borodic to be a functional equivalent to Clostridium botulinum toxin type A when used in a method of treating inflammatory skin wounds that are adversely effected by muscle tension and movement (see Gassner col. 3, lines 6-9 and lines 37-38).

In the absence of a showing of unexpected results, the person of ordinary skill in the art would have been motivated by the reasonable expectation of success of treating a pressure sore with the Clostridium botulinum toxin type A of Gassner et al in the composition of Rebar et al because Rebar et al teach that Clostridium toxins are useful in compositions for treating pressure sores (see Rebar et al, [0310] and[0275-276]) and the Clostridial toxin containing compositions together with a ZFP fusion protein are taught to provide for wound healing (see Rebar et al, [0310] and the Clostridium toxin serves to translocate the composition across a cell membrane to insure the desired biological effect of treating pressure sores is accomplished. Rebar et al in view of Borodic and Gassner et al obviate the instantly claimed invention as now claimed.

2. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ginny Portner whose telephone number is (571) 272-0862. The examiner can normally be reached on flextime, but usually M-F, alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Siew can be reached on (571) 272-0787. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Vgp
June 13, 2007

MARK NAVARRO
PRIMARY EXAMINER